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27/Brief

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RAYMOND W. GREEN
Registered Representative

Signature

Date of Signature: January 12, 2004

PATENT
BHG&L Case 8627/405

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kieran P. J. Murphy	:	
Serial No.:	09/594,685	:	
Filed:	June 16, 2000	:	Group Art Unit: 3732
For:	METHOD AND APPARATUS FOR STRENGTHENING VERTABRAL BODIES	:	Examiner: Eduardo C. Robert

MAIN BRIEF ON APPEAL TO THE
BOARD OF PATENT APPEALS AND INTERFERENCES

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Sir:

(1) REAL PARTY IN INTEREST

The inventor has not assigned his entire interests in the invention, and hence a real party in interest is Applicant Kieran P. J. Murphy. The inventor has, however, granted rights in the invention (not shown by documents of record in the Patent and Trademark Office) to Cook Incorporated of Bloomington, Indiana, which is another real party in interest.

(2) CONTENTS

(3) RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

(4) STATUS OF CLAIMS

The claims presented are 1-21. All claims are rejected. No claims have been cancelled. No claims have been allowed. The rejection of all claims is appealed.

(5) STATUS OF AMENDMENTS

No amendment has been filed since the Final Rejection of August 8, 2003. No amendment remains unentered.

(6) SUMMARY OF INVENTION

The invention as claimed in Claims 1-16 is a tray of vertebroplasty components for use in performing vertebroplasty (surgery of the vertebrae), including a collection of components that Appellant has found to be useful for a surgeon intending to perform vertebroplasty. The components include a local anaesthesia assembly (Figure 4, item 61); a bone cement assembly (item 80); a surgical cutting instrument such as a scalpel (item 71); and a device for injection of hardenable liquid biomaterial into a vertebral body, such as a vertebroplasty needle (item 73). Components recited in dependent claims 2-16 include a container of a local anaesthesia (item 63); a local anaesthesia aspiration syringe (item 65); a local anaesthesia aspiration needle (item 67); a local anaesthesia injection needle (item 69); a container of a liquid monomer (item 82); a monomer aspiration needle (item 85); a monomer aspiration syringe (item 84); a mixing bowl (item 86); a mixing spatula (item 88); a container of polymer powder such as methylmethacrylate (item 90); and an opacifier (item 92). Claim 20 recites the same ultimate components, but not the intermediate local anaesthesia assembly and bone cement assembly. Claim 21 recites the same hardware components, but not the materials that are mixed to make the cement (monomer, polymer powder and opacifier). No prior art reference or combination of references applied by the Examiner teaches or suggests the combinations of components claimed in claims 1-16 and 20-21.

The invention as claimed in Claims 17-19 is a vertebroplasty kit (Figure 4, item 55) comprising two trays (items 57 and 59) of vertebroplasty components, which may be individually assembled and packaged (claim 18) and kept sterile until use in performing vertebroplasty (claim 19). The two trays are arranged so that the first tray of components can be used to perform a first vertebroplasty injection through a first pedicle of a vertebral body (claim 17, lines 3-4), and then the second tray of components can either (a) be used to perform a second vertebroplasty injection through a second pedicle

of a vertebral body, if it is determined that the first vertebroplasty injection did not sufficiently strengthen the vertebral body; or (b) remain sterile for use in another vertebral body if said first vertebroplasty injection is determined to have sufficiently strengthened the vertebral body (claim 17, lines 7-9). No prior art reference or combination of references applied by the Examiner teaches or suggests the two-tray configuration claimed in claims 17-19, arranged so that the first tray of components can be used to perform a first vertebroplasty injection, and then the second tray of components can either (a) be used to perform a second vertebroplasty injection, or (b) remain sterile for use in another vertebral body.

(7) ISSUES PRESENTED

Stated in the format suggested by MPEP § 1206, the issues on appeal are:

1. Whether Claims 17-19 are unpatentable under 35 USC 102(b) as anticipated by Lazarus et al. U.S. Patent 4,128,173?

2. Whether Claims 17 and 18 are unpatentable under 35 USC 102(b) as anticipated by Partika et al. U.S. Patent 5,779,053?

3. Whether Claims 1-16, 20 and 21 are unpatentable under 35 USC 103(b) as obvious from the combined teachings of Folkman U.S. Design Patent D 213,934, in view of Shanley et al. U.S. Patent 5,626,230; MacLeod et al. U.S. Patent 5,506,257; Smith et al. U.S. Patent 5,690,618; Arlers U.S. Patent 3,910,273; Racz U.S. Patent 5,817,074; Jiang et al. U.S. Patent 5,847,046; Singer U.S. Patent 5,147,308; Draenert U.S. Patent 5,645,347; Haynie U.S. Patent 5,240,415; Hertzmann et al. U.S. Patent 5,084,043; and Baker U.S. Patent 4,554,686?

Subsidiary issues that may assist the Board in determining whether the claims are anticipated by or obvious from the applied references are the following:

(a) Does the prior art teach or suggest the *combinations* claimed in claims 1-16, 20 and 21?

(b) Does the prior art teach the two-tray configuration claimed in claims 17-19, arranged so that the first tray of components can be used to perform a first vertebroplasty injection, and then the second tray of components can either (a) be used to perform a second vertebroplasty injection, or (b) remain sterile for use in another vertebral body?

(8) GROUPING OF CLAIMS

The Examiner has grouped the claims in three groups, as follows (group numbers assigned by Appellant):

Group I – Claims 17 and 18 – alleged to be anticipated by both Lazarus and Partika.

Group II – Claim 19 – alleged to be anticipated by Lazarus, but not by Partika.

Group III – Claims 1-16, 20 and 21 – alleged to be rendered obvious by the combined teachings of Folkman in view of Shanley, MacLeod et al., Smith et al., Arlers, Racz, Jiang et al., Singer, Draenert, Haynie, Hertzmann et al. and Baker.

Appellant accepts this grouping of the claims.

(9) ARGUMENT

A. THE PRIOR ART DOES NOT TEACH OR SUGGEST THE *COMBINATIONS* CLAIMED IN CLAIMS 1-16, 20 AND 21.

Claims 1-16, 20 and 21 are rejected as unpatentable (obvious) over Folkman in view of Shanley, MacLeod et al., Smith et al., Arlers, Racz, Jiang et al., Singer, Draenert, Haynie, Hertzmann et al. and Baker.

The Examiner has used Appellant's claims as a shopping list to find a patent that teaches each *element* in the combination, but has not cited or applied a reference that teaches the *combination* itself. The Examiner has not cited column and line for most of the teachings alleged to be relevant, but the relevant portions of the references appear to be as follows:

Folkman is a design of "Tray for Medical Equipment" (title). Folkman does not say what goes in the tray.

Shanley appears to be relevant at column 1, lines 1-17. Shanley discloses a kit of 6 different "sharps" for use in catheterization by the Seldinger technique (percutaneous insertion of a catheter into an artery or vein), which typically requires the handling of 6 different sharps (3 needles, items 4-6; a scalpel, item 7; a 2-part needle of inner stylet, item 11 and outer cannula, item 12).

MacLeod appears to be relevant at column 3, lines 18-23. MacLeod discloses a kit containing a chemical that can be used to induce local anaesthesia.

Smith appears to be relevant at the abstract, lines 1-4 and in column 1, lines 18-20. Smith discloses an electronic syringe for administering anesthetic or aspirating fluids, intended for dental applications. The Examiner cited column 9, lines 9-11, which disclose that the electronic syringe can be used for aspiration (withdrawal from the body) of body fluids.

Arlers appears to be relevant in the title, "Aspirating ... Syringe". The syringe is for injection of anaesthetics following aspiration of body fluids.

Racz appears to be relevant at column 1, lines 7-8. Racz discloses a needle for aspiration.

Jiang appears to be relevant in the title, "Biodegradable bone cement"; in column 1, lines 1-22, which disclose that a liquid monomer for use with polymer powder in repairing bone can be methyl methacrylate with dimethyl toluidine and hydroquinone; and in column 2, lines 40-47, which disclose that these can be included in a kit, which includes only chemicals.

Singer appears to be relevant at column 1, lines 5-34. Singer discloses an aspiration needle for withdrawing fluids from various parts of the body.

Draenert appears to be relevant at column 1, lines 11-15, where Draenert discloses mixing apparatus for making bone cement; at column 1, lines 66-67, where Draenert discloses a bowl and spatula; at column 2, lines 1-3, where Draenert discloses that bone cement can be applied with syringe; at column 5, lines 25-30, where Draenert discloses a bowl and applicator of polyolefin or polycarbonate; and at column 6, lines 15-17, where Draenert discloses that bone cement can be made from monomer and polymer powder.

Haynie appears to be relevant in the Abstract, where Haynie discloses that a dental bleach patient use kit can include fumed silica and hydrogen peroxide; and at column 5, lines 34-39 and in Figure 1, where Haynie discloses that such a kit can include a spatula 24.

Hertzmann appears to be relevant at column 15, lines 44-51, where Hertzmann discloses that a kit for diskectomy using a laser can include a scalpel (column 15, line 50).

Baker appears to be relevant at column 1, lines 36-38, where Baker discloses that barium sulfate is radiopaque, and serves as opacifier in bone cements.

None of the applied references, however, teaches or suggests the *combinations* claimed in Claims 1-16, 20 and 21.

35 USC 103(a) describes nonobvious subject matter as a condition for patentability. An invention is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person of ordinary skill in the art ...." (emphasis supplied). The invention *as a whole* must have been obvious to sustain a rejection under 35 USC 103(a), not just the individual pieces. The Examiner errs in failing to consider the invention as a whole.

MPEP § 2143.01 (8th ed., Rev. 1, Feb.2003), pages 2100-125ff, provides an explanation of when obviousness rejections are proper and when they are improper. As there explained, if a combination of references teaches every element of a claimed combination, but there is no motivation to combine the elements to make the claimed combination, the references do not support an obviousness rejection, citing *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). MPEP § 2143.01, page 2100-125.

> " 'In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference[s] before him to make the proposed ... combination ....' *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

> "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is **some teaching, suggestion, or motivation to do so** found either explicitly or implicitly ...."

MPEP § 2143.01, page 2100-125, emphasis supplied.

> "The mere fact that references can be combined or modified does not render the resultant combination obvious **unless the prior art also suggests the desirability of the combination**. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)"

MPEP § 2143.01, page 2100-126, underlining in MPEP, bold emphasis supplied.

> "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill of the art at the time the invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness **without some objective reason to combine the teachings of the references**. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). ..."

MPEP § 2143.01, page 2100-126, underlining and italics in MPEP, bold emphasis supplied.

A suggestion, teaching or motivation to combine the prior art references is an essential component of an obviousness determination. The Examiner has not supplied such a suggestion, teaching or motivation.

When a patent (application) describes a new mechanical device that can be viewed as a new combination or arrangement of mechanical components, the legal conclusion of obviousness requires that there be some suggestion, motivation or teaching in the prior art whereby the person of ordinary skill in the art would have selected the components that the inventor selected, and used them to make the new device. *C.R. Bard Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1351, 48 USPQ2d 1225, 1231, *rehearing, en banc, denied*, 49 USPQ2d 1319 (Fed. Cir. 1998), *cert. denied*, 526 U.S. 1130 (1999). There must have been something in the prior art to suggest the desirability, and thus the obviousness, of making the combination. *Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994).

CASES CITED BY THE EXAMINER

1. *In re Leshin*

The Examiner has cited *In re Leshin*, 277 F.2d 197, 125 USPQ 416 (CCPA 1960) at page 4 of the final rejection, for the proposition that, with respect to claim 13, it is "within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice." (277 F.2d at 198-99, 125 USPQ at 417-18.) Claim 13 does not depend for patentability on the selection of the polymer powder being methylmethacrylate, but rather claim 13 depends from claims 1 and 11. The Examiner has not shown that the prior art provides motivation to combine the elements to make the combination claimed in claims 1 and 11, so the combination of claim 13 is patentable, as well. Accordingly, the rejection should be *REVERSED*.

2. *Ex parte Masham*

The Examiner has cited *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987) at pages 5, 6 and 7 of the final rejection, for the proposition that "the manner in which a device is intended to be employed does not differentiate the claimed invention from the **prior art apparatus satisfying the claimed structural limitations**" (emphasis by Examiner deleted, bold emphasis supplied), both in support of the rejections under 35 USC 102 and the rejections under 35 USC 103. In other words, **if the device is old**, how the inventor intends to use the device in a new manner does not make it a new device. But the Examiner still needs to show that the device as claimed is old, *i.e.*, that the **prior art apparatus satisfies the claimed structural limitations**. As explained above, showing that the components are old is not enough. There must be **motivation to combine the elements to make the claimed combination**, in order for the references to support an obviousness rejection. The Examiner has not shown that the prior art provides motivation to combine the elements to make the claimed combination. Accordingly, the rejection should be *REVERSED*.

3. *Kropa v. Robie*

The Examiner has cited *Kropa v. Robie and Mahlman*, 187 F.2d 150, 88 USPQ 478 (CCPA 1951) at page 5 of the final rejection, for the proposition that preamble limitations

are given no weight **where the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness on the introductory clause**. However, *Kropa v. Robie* also stated that the words "An abrasive article" that constituted the preamble under consideration were "essential to point out the [defined] invention", and that those "introductory words give life and meaning to the [interference] counts [or claims], for it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article." 187 F.2d at 152, 88 USPQ at 481. The Court then held that the words "An abrasive article" were a **"limitation which is material to the issue, and must be observed."** 187 F.2d at 152, 88 USPQ at 481, bold emphasis supplied.

In the present case, the Examiner also intends to disregard all statements of intended use. By so construing the claim, the Examiner transforms claim 1 to the following:

TRANSFORMED CLAIM 1A (Claim 1, with intended uses bracketed):

A tray of vertebroplasty components [for use in performing vertebroplasty], said tray comprising:

a local anaesthesia assembly [for producing a reversible loss of sensation in a surgical area proximate to a vertebral body];

a bone cement assembly [for preparation of a hardenable liquid biomaterial for strengthening said vertebral body];

a surgical cutting instrument [for providing cutaneous incision in said surgical area proximate to said vertebral body]; and

a device [for injection of said hardenable liquid biomaterial into said vertebral body].

Deleting the five "for" clauses, shown above in brackets, gives the following construction:

TRANSFORMED CLAIM 1B (Claim 1, with intended uses deleted):

A tray of vertebroplasty components, said tray comprising:

a local anaesthesia assembly;
a bone cement assembly;
a surgical cutting instrument; and
a device.

If the preamble is further disregarded, the following construction results:

TRANSFORMED CLAIM 1C (Claim 1, with preamble and intended uses deleted):

A local anaesthesia assembly;
a bone cement assembly;
a surgical cutting instrument; and
a device.

Certainly the preamble is necessary in the present case, as it is essential to point out the defined invention, and those words give life and meaning to the claims, for it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as a tray of vertebroplasty components.

Accordingly, while the proposition that preamble limitations are given no weight **where the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness on the introductory clause** appears to be good law (although *dicta* in *Kropa v. Robie*), it is also the law that when the preamble is essential to point out the defined invention, and those words give life and meaning to the claims, such as when it is only by that phrase that it can be known what the subject matter defined by the claims is, preambles are a "limitation which is material to the issue, and must be observed." 187 F.2d at 152, 88 USPQ at 481. Accordingly, in this case, the preamble should be considered a part of the claim that must be suggested by the prior art.
Even if the preamble is disregarded, however, the Examiner has not shown that the prior art provides motivation to combine the elements to make *even* the combination recited in Transformed Claim 1C, above. Accordingly, the rejection should be *REVERSED*.

4. *In re McLaughlin*

The Examiner has cited *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971) at page 6 of the final rejection, for the propositions that any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, and as long as such a reconstruction takes into account only knowledge which was within the level of ordinary skill at the time the invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. (443 F.2d at 1395, 170 USPQ at 212.) *In re McLaughlin* went on to analyze the references, and found them to suggest the combination in question. In distinction, the Examiner in this Application just says "... because the individual components are known in the prior art, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have any of these components available at the same time, e.g. as in a 'kit'.... [M]erely combining the components of applicant's kit or tray are already available as prior art, merely combining the components under the rubric of a 'kit' or 'tray' does not result in a novel invention, even taken as a whole. ..." Final Rejection, pages 3-4.

Clearly the Examiner is mis-applying *In re McLaughlin.* Applicant's invention is surely novel, because it took twelve references to show all the components. The question in an obviousness rejection is not whether the claims claim novel subject matter, for it is assumed in an obviousness rejection that the claims do claim novel subject matter, the question being whether the novel combination is unobvious. The only suggestion to combine the references applied by the Examiner, which is given by the Examiner, is the fact that all of the components were individually available in the prior art. That of course is no suggestion at all of the *combination.* The rejection should therefore be *REVERSED.*

5. *In re Fine and In re Jones*

The Examiner has cited *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992) at page 7 of the final rejection, for the proposition that the rationale to modify or combine the prior art

does not have to be expressly stated in the prior art, the rationale to modify may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. From this assertion, one would think the Examiner had shown a rationale to combine the prior art impliedly contained in the prior art or reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. However, the Examiner has not done so. He just says, in effect, the pieces are in the prior art, and it would *ipso facto* be obvious to combine them.

In re Fine says that

> "The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. [Citing case.] It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. [Citing cases.] This it has not done. The Board points to nothing in the cited references, either alone or in combination, suggesting or teaching Fine's invention."

837 F.2d at 1074, 5 USPQ2d at 1598-99.

This quotation from *In re Fine* is directly applicable to the present appeal. The Examiner has the burden under section 103 to establish a *prima facie* case of obviousness. The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This the Examiner has not done. The Examiner points to nothing in the cited references, either alone or in combination, suggesting or teaching Appellant Murphy's invention.

In re Jones says that

> "Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837

> F.2d 1071, 1074, 5 USPQ2d 1596, 1589-99 (Fed. Cir. 1988). We see no such suggestion in [the prior art].
>
> "Conspicuously missing from the record is any *evidence*, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the ... art would have been motivated to make the modifications of the prior art ... necessary to arrive at the claimed [invention]. ...
>
> "We conclude that the PTO did not establish a *prima facie* case of obviousness, and thus did not shift the burden of coming forward with unexpected results or other objective evidence of non-obviousness. Accordingly, the decision of the Board is
>
> "*REVERSED.*"

958 F.2d at 351, 21 USPQ2d at 1943-44.

This quotation from *In re Jones* is also directly applicable to the present appeal. Before the Examiner may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Examiner has cited no such suggestion in the prior art.

Conspicuously missing from the record is any *evidence*, other than the Examiner's speculation (if it be called evidence) that one of ordinary skill in the art would have been motivated to make the modifications of the prior art necessary to arrive at the claimed invention.

The Board should conclude that the Examiner did not establish a *prima facie* case of obviousness, and thus did not shift the burden of coming forward with unexpected results or other objective evidence of non-obviousness. Accordingly, the decision of the Examiner should be *REVERSED.*

B. THE PRIOR ART DOES NOT TEACH OR SUGGEST THE TWO-TRAY CONFIGURATION CLAIMED IN CLAIMS 17-19, ARRANGED SO THAT THE FIRST TRAY OF COMPONENTS CAN BE USED TO PERFORM A FIRST VERTEBROPLASTY INJECTION, AND THEN THE SECOND TRAY OF COMPONENTS CAN EITHER (A) BE USED TO PERFORM A SECOND VERTEBROPLASTY INJECTION, OR (B) REMAIN STERILE FOR USE IN ANOTHER VERTEBRAL BODY.

Claim 17 recites:

17. A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, **such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body**.

(Emphasis supplied.)

Claims 17-19 are rejected under 35 USC 102(b) as anticipated by Lazarus et al. U.S. Patent 4,128,173. The Examiner explains that Lazarus et al. "disclose a kit 10 comprising a first tray 10a of components and a second tray 10b of components. The first and second tray[s] are individually assembled and packaged and are kept sterile until use." (Final rejection, page 2.)

Lazarus relates to a "Peritoneal Fluid Treatment Apparatus, Package and Method." (Title.) Lazarus teaches that "Apparatus to effect peritoneal fluid treatment are placed in sterile openable sealed packages for storage and transport." (Abstract, last 3 lines.) The package is illustrated in Lazarus's Figure 1.

The disclosure of Lazarus that appears to be relied on by the Examiner appears at Figure 1 and at column 7, lines 36-51:

"Although all the materials and apparatus can be placed in one package, it is regarded as most preferred to place the catheter 12, wire guide 14 and cannula 16 in

one half 10a, and the drape 32, sponges 30, syringe 36 and needle 38, anesthetic 104, knife 40 and suture 80 and needle 81 in a second half 10b of the package 10. The two halves 10a, 10b are each separately sealed and openable and separable from each other by tearing along a perforation indicated by the broken line 130. Thus the materials for peritoneal fluid treatment are assembled into one kit ready for instant use. The package 10 can be unitarily stored and transported into its halves 10a, 10b for ease of use, by the physician opening each half and individual packages in order of use to minimize exposure to the environment and potential loss of sterility by the contents."

The Lazarus apparatus does not have "vertebroplasty injection components", recited in claim 17, lines 3 and 5, in either tray.

Lazarus does not meet the "such that" clause of claim 17, *i.e.*, the Lazarus apparatus is not arranged "**such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body**".

Lazarus likewise does not meet the last three words in claim 19, *i.e.*, the Lazarus apparatus trays are not kept "sterile until use **in performing vertebroplasty**".

Neither Lazarus, nor any other prior art reference or combination of references applied by the Examiner, teaches or suggests the two-tray configuration claimed in claims 17-19, arranged so that the first tray of components can be used to perform a first vertebroplasty injection, and then the second tray of components can either (a) be used to perform a second vertebroplasty injection, or (b) remain sterile for use in another vertebral body.

The anticipation rejection based on Lazarus should be *REVERSED.*

Claims 17 and 18 are rejected under 35 USC 102(b) as anticipated by Partika et al. U.S. Patent 5,779,053. The Examiner explains that Partika et al. "disclose a kit comprising a first and second tray of components (see Figure 2) which are individually assembled and packaged and kept sterile until use." (Final rejection, page 2.)

The disclosure of Partika that appears to be relied on by the Examiner, in addition to Figure 2, appears at column 4, lines 20-39:

> "Skin preparation tray 10 may be configured as a removable component of a surgical kit 12. As shown in FIG. 2, surgical kit 12 may feature various implements 14, such as syringes, blood collection tubes, and the like, utilized for a given surgical procedure. The skin preparation tray may be retained in surgical kit 12 in a recessed portion 16 shaped to accommodate the particular shape and structure imparted to various portions of skin preparation tray 10. In one configuration, rim portion 23 of planar sheet 20 may be supported by a ledge portion 17 in surgical kit 12. As thus configured, the skin preparation tray may be contained within surgical kit 12 in a co-planar manner with a perimeter portion 21 of the surgical kit. If desired, spacers 25 may be incorporated on the surface of sheet 20 to help isolate skin preparation tray 10 and the various implements held thereby from gauzes, wraps, pads or other items (not shown) which may be placed over the tray in completing surgical kit 12. The overall design of surgical kit 12 and skin preparation tray 10 promotes compactness, together with ease of packaging and handling."

The Partika apparatus has a skin preparation tray 10 as a component of surgical kit 12, not two surgical component trays.

The Partika apparatus does not have "vertebroplasty injection components", recited in claim 17, lines 3 and 5, in either tray.

Partika does not meet the "such that" clause of claim 17, *i.e.*, the Partika apparatus is not arranged "**such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body**".

Neither Partika, nor any other prior art reference or combination of references applied by the Examiner, teaches or suggests the two-tray configuration claimed in claims 17 and 18, arranged so that the first tray of components can be used to perform a first vertebroplasty injection, and then the second tray of components can either (a) be used to

perform a second vertebroplasty injection, or (b) remain sterile for use in another vertebral body.

The anticipation rejection based on Partika should be *REVERSED.*

(10) SUMMARY

With respect to claims 1-16, 20 and 21, rejected as obvious over a combination of twelve references, the Examiner has used Appellant's claims as a shopping list to find a patent that teaches each *element* in the combination, but has not cited or applied a reference that teaches the *combination* itself. Numerous cases, a few of which are discussed in this Brief, have held that in rejecting a claim directed to a combination of elements, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so, and the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. Accordingly, the rejection of claims 1-16, 20 and 21 should be *REVERSED.*

With respect to claims 17 and 18, rejected as anticipated by each of two references, and 19, rejected as anticipated by one reference, the Examiner has ignored key recitations in the claims. Accordingly, the rejection of claims 17-19 should be *REVERSED.*

The Examiner has ignored the majority of the claim language that gives life and meaning to the claims, and found references that suggest the framework within which the definition of the claimed invention is set. The Examiner has not found references that teach or suggest the invention itself.

The cases cited by the Examiner, while stating correct legal principles, actually more often support the Appellant than the position the Examiner is taking.

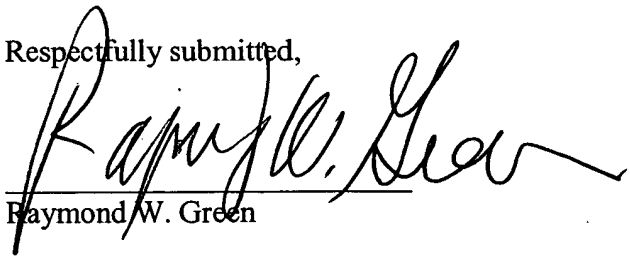
The Examiner has not carried his burden of proof in establishing a *prima facie* case for unpatentability of any claim.

Accordingly, the rejections of claims 1-21 should all be *REVERSED.*

(11) CONCLUSION

All of the rejections applied by the Examiner should be *REVERSED.*

Respectfully submitted,



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(12) APPENDIX – APPEALLED CLAIMS:

1. A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia assembly for producing a reversible loss of sensation in a surgical area proximate to a vertebral body;

a bone cement assembly for preparation of a hardenable liquid biomaterial for strengthening said vertebral body;

a surgical cutting instrument for providing cutaneous incision in said surgical area proximate to said vertebral body; and

a device for injection of said hardenable liquid biomaterial into said vertebral body.

2. The tray according to claim 1, wherein said local anaesthesia assembly includes at least one container of a local anaesthesia.

3. The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration syringe.

4. The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia aspiration needle.

5. The tray according to claim 1, wherein said local anaesthesia assembly includes at least one local anaesthesia injection needle.

6. The tray according to claim 1, wherein said bone cement assembly includes at least one container of a liquid monomer.

7. The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration needle.

8. The tray according to claim 1, wherein said bone cement assembly includes at least one monomer aspiration syringe.

9. The tray according to claim 1, wherein said bone cement assembly includes at least one mixing bowl.

10. The tray according to claim 1, wherein said bone cement assembly includes at least one mixing spatula.

11. The tray according to claim 1, wherein said bone cement assembly includes at least one container of polymer powder.

12. The tray according to claim 1, wherein said bone cement assembly includes an opacifier.

13. The tray according to claim 11, wherein said polymer powder is methylmethacrylate.

14. The tray according to claim 11, wherein said polymer powder in said hardenable liquid biomaterial is from about five grams to about forty grams of methylmethacrylate.

15. The tray according to claim 11, wherein said surgical cutting instrument is a scalpel.

16. The tray according to claim 11, wherein said device for injection is a vertebroplasty needle.

17. A vertebroplasty kit for use in performing vertebroplasty, said vertebroplasty kit comprising:

a first tray of vertebroplasty injection components for performing a first vertebroplasty injection through a first pedicle of a vertebral body;

a second tray of vertebroplasty injection components for performing a second vertebroplasty injection through a second pedicle of said vertebral body, such that said second tray of vertebroplasty injection components can remain sterile for use in another vertebral body if said first vertebroplasty injection sufficiently strengthens said vertebral body.

18. The kit according to claim 17, wherein said first tray and said second tray are individually assembled and packaged.

19. The kit according to claim 18, wherein said first tray and said second tray are sterile until use in performing vertebroplasty.

20. A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a liquid monomer;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a polymer powder;

an opacifier;

a scalpel; and

a vertebroplasty needle.

21. A tray of vertebroplasty components for use in performing vertebroplasty, said tray comprising:

a local anaesthesia;

a local anaesthesia aspiration syringe;

a local anaesthesia aspiration needle;

a local anaesthesia injection needle;

a monomer aspiration needle;

a monomer aspiration syringe;

a mixing bowl;

a mixing spatula;

a scalpel; and

a vertebroplasty needle.